

WHAT IS CLAIMED IS:

1. A system for producing a custom prosthetic liner, comprising:
  - a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;
  - a processing device for generating a 3-dimensional electronic liner model using said 3-dimensional shape captured by said shape capture apparatus, said processing device optionally adapted to generate a 3-dimensional electronic residual limb model;
  - a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner;
  - an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both; and
  - a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.
2. The system of claim 1, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.
3. The system of claim 1, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

4. The system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.
5. The system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is remotely transmitted to said facility equipped to produce said custom liner.
6. The system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).
7. The system of claim 1, wherein said at least one custom mold component is produced from said data by a computer-controlled machining device.
8. The system of claim 1, wherein said at least one custom mold component is created from a closed-cell foam material.
9. The system of claim 1, wherein said at least one custom mold component is a mold core for use with a common mold cavity.
10. The system of claim 9, wherein said mold cavity is selected based on its size.
11. The system of claim 1, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.
12. The system of claim 1, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

13. The system of claim 12, wherein said custom prosthetic liner is manufactured from a block copolymer material.
14. The system of claim 1, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.
15. The system of claim 1, further comprising the ability to modify the shape of either or both of said 3-dimensional electronic models to accommodate particular features of said residual limb in said custom prosthetic liner.
16. The system of claim 1, further comprising the ability to select liner materials and material properties.
17. The system of claim 1, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.
18. The system of claim 17, wherein the number, location, and orientation of said accessories may be specified.
19. The system of claim 17, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.
20. The system of claim 18, wherein said additives include anti-microbial substances.
21. The system of claim 1, further comprising a means of communication with an automated system for configuring and purchasing a medical device.
22. A method for producing a custom prosthetic liner, comprising:

using a shape capture apparatus to capture the 3-dimensional shape of an amputee's residual limb;

using a processing device to generate a 3-dimensional electronic liner model from the captured shape;

optionally, using said processing device to generate a 3-dimensional electronic residual limb model from the captured shape;

providing a means of furnishing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner;

creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both; and

using a molding machine to produce said custom prosthetic liner from a mold incorporating said at least one custom mold component.

23. The method of claim 22, wherein said means for capturing the 3-dimensional shape of an amputee's residual limb is a multiple image detector shape capture device.

24. The method of claim 22, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

25. The method of claim 22, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

26. The method of claim 22, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

27. The method of claim 22, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

28. The method of claim 22, wherein said at least one custom mold component is produced from said data by a computer-controlled machining device.

29. The method of claim 22, wherein said at least one custom mold component is created from a closed-cell foam material.

30. The method of claim 22, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

31. The method of claim 30, wherein said mold cavity is selected based on its size.

32. The method of claim 22, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

33. The method of claim 22, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.
34. The method of claim 33, wherein said custom prosthetic liner is manufactured from a block copolymer material.
35. The method of claim 22, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.
36. The method of claim 22, further comprising providing the ability to manipulate the shape of either or both of said 3-dimensional electronic liner and residual limb models to accommodate particular features of said residual limb in said custom prosthetic liner.
37. The method of claim 22, further comprising providing the ability to select liner materials and material properties.
38. The method of claim 22, further comprising providing the ability to specify accessories to be included in/on said custom prosthetic liner.
39. The method of claim 38, wherein the number, location, and orientation of said accessories may also be specified.
40. The method of claim 38, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.
41. The method of claim 40, wherein said additives include anti-microbial substances.

42. The method of claim 22, further comprising a providing a means of communication with an automated system for configuring and purchasing a medical device.

43. A system for producing a custom prosthetic liner, comprising:

- a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

- a storage means in communication with said shape capture apparatus for temporarily storing data associated with said 3-dimensional shape of an amputee's residual limb;

- a means of providing said data to a facility equipped to produce said custom prosthetic liner;

- a means at said facility for associating prosthetic liner parameters with said data;

- an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional shape of an amputee's residual limb and said prosthetic liner parameters; and

- a molding machine for forming said custom prosthetic liner from a mold incorporating said at least one custom mold component.

44. The system of claim 43, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

45. The system of claim 43, wherein said storage means stores said data associated with the captured 3-dimensional shape of an amputee's residual limb on

a machine readable medium for subsequent delivery to said facility equipped to produce said custom liner.

46. The system of claim 43, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is remotely transmitted to said facility equipped to produce said custom liner.

47. The system of claim 43, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

48. The system of claim 43, further comprising a processing device in communication with said shape capture apparatus, said processing device for generating a 3-dimensional electronic model of said residual limb from said 3-dimensional shape captured by said shape capture apparatus

49. The system of claim 48, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

50. The system of claim 43, further comprising a means for generating numerical data representative of said 3-dimensional model.

51. The system of claim 50, wherein said numerical data is generated after delivery of said data associated with the captured 3-dimensional shape of an amputee's residual limb to said facility equipped to produce said custom liner.



52. The system of claim 50, wherein said numerical data is generated by said shape capture apparatus or a device in communication with said shape capture apparatus, and said numerical data is subsequently provided to said facility equipped to produce said custom liner.

53. The system of claim 43, wherein said at least one custom mold component is produced by a computer-controlled machining device.

54. The system of claim 43, wherein said at least one custom mold component is created from a closed-cell foam material.

55. The system of claim 43, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

56. The system of claim 55, wherein said mold cavity is selected based on its size.

57. The system of claim 43, wherein said at least one custom mold component is a custom mold cavity for use with a custom or common mold cavity.

58. The system of claim 43, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

59. The system of claim 58, wherein said custom prosthetic liner is manufactured from a block copolymer material.

60. The system of claim 43, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

61. The system of claim 43, further comprising the ability to manipulate said data associated with said 3-dimensional shape of an amputee's residual limb in order to accommodate particular features of said residual limb in said custom prosthetic liner.
62. The system of claim 43, further comprising the ability to select liner materials and material properties.
63. The system of claim 43, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.
64. The system of claim 63, wherein the number, location, and orientation of said accessories may also be specified.
65. The system of claim 63, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.
66. The system of claim 65, wherein said additives include anti-microbial substances.
67. The system of claim 43, further comprising a means of communication with an automated system for configuring and purchasing a medical device.
68. A method of producing a custom prosthetic liner, comprising:
- using a shape capture apparatus to capture the 3-dimensional shape of an amputee's residual limb;
  - providing a storage means in communication with said shape capture apparatus for temporarily storing data associated with said 3-dimensional shape of an amputee's residual limb;

providing a means of furnishing said data to a facility equipped to produce said custom prosthetic liner;

providing a means at said facility for associating prosthetic liner parameters with said data;

creating at least one custom mold component from said data associated with said 3-dimensional shape of an amputee's residual limb and said prosthetic liner parameters; and

using a molding machine to produce said custom prosthetic liner from a mold incorporating said at least one custom mold component.

69. The method of claim 68, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

70. The method of claim 68, wherein said storage means stores said data associated with the captured 3-dimensional shape of an amputee's residual limb on a machine readable medium for subsequent delivery to said facility equipped to produce said custom liner.

71. The method of claim 68, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is remotely transmitted to said facility equipped to produce said custom liner.

72. The method of claim 68, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

73. The method of claim 68, further comprising providing a processing device in communication with said shape capture apparatus, said processing device for generating a 3-dimensional electronic model of said residual limb from said 3-dimensional shape captured by said shape capture apparatus

74. The method of claim 68, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

75. The method of claim 68, further comprising a means for generating numerical data representative of said 3-dimensional model.

76. The method of claim 75, wherein said numerical data is generated after delivery of said data associated with the captured 3-dimensional shape of an amputee's residual limb to said facility equipped to produce said custom liner.

77. The method of claim 75, wherein said numerical data is generated by said shape capture apparatus or a device in communication with said shape capture apparatus, and said numerical data is subsequently provided to said facility equipped to produce said custom liner.

78. The method of claim 68, wherein said at least one custom mold component is produced by a computer-controlled machining device.

79. The method of claim 68, wherein said at least one custom mold component is created from a closed-cell foam material.

80. The method of claim 68, wherein said at least one custom mold component is a mold core for use with a common mold cavity.
81. The method of claim 80, wherein said mold cavity is selected based on its size.
82. The method of claim 68, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.
83. The method of claim 68, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.
84. The method of claim 83, wherein said custom prosthetic liner is manufactured from a block copolymer material.
85. The method of claim 68, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.
86. The method of claim 68, further comprising the ability to manipulate the data associated with said 3-dimensional shape of an amputee's residual limb to accommodate particular features of said residual limb in said custom prosthetic liner.
87. The method of claim 68, further comprising providing the ability to select liner materials and material properties.
88. The method of claim 68, further comprising providing the ability to specify accessories to be included in/on said custom prosthetic liner.
89. The method of claim 88, wherein the number, location, and orientation of said accessories may also be specified.

90. The method of claim 88, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

91. The method of claim 90, wherein said additives include anti-microbial substances.

92. The method of claim 68, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

93. A system for producing a custom prosthetic liner, comprising:

- a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

- a processing device running a computer program for generating a 3-dimensional electronic residual limb model from said 3-dimensional shape captured by said shape capture apparatus, said processing device and computer program further adapted to generate a 3-dimensional electronic liner model from said residual limb model and input liner parameters;

- an interface for allowing a user of said system to operate said computer program to modify said 3-dimensional electronic residual limb model, said 3-dimensional electronic liner model, or both, if so desired;

- an interface for allowing a user of said system to specify liner parameters;

optionally, an interface for allowing a user of said system to communicate with a separate system and computer program that facilitates the automatic configuration and purchasing of a medical device;

a storage device for temporarily storing data associated with said 3-dimensional electronic residual limb model and said 3-dimensional electronic liner model;

a transmission device for allowing data associated with a finalized version of said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to be remotely sent to a manufacturing facility equipped to produce said custom prosthetic liner;

a means at said manufacturing facility for receiving said data associated with said finalized version of said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, and for reading said data or converting said data into a readable form;

an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both; and

a molding machine for forming said custom prosthetic liner from a mold incorporating said at least one custom mold component.

94. The system of claim 93, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

95. The system of claim 93, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

96. The system of claim 93, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility via the Internet.

97. The system of claim 93, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

98. The system of claim 93, wherein said means for temporarily storing said data associated with said 3-dimensional electronic liner model and said 3-dimensional electronic residual limb model is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

99. The system of claim 93, wherein said transmission means is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth<sup>®</sup> card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

100. The system of claim 93, wherein said at least one custom mold component is a mold core for use with a common mold cavity.



101. The system of claim 100, wherein said mold cavity is selected based on its size.
102. The system of claim 93, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.
103. The system of claim 93, further comprising the ability to use said computer program to select liner materials and material properties.
104. The system of claim 93, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.
105. The system of claim 104, wherein the number, location, and orientation of said accessories may also be specified.
106. The system of claim 104, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.
107. The system of claim 106, wherein said additives include anti-microbial substances.
108. The system of claim 93, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.
109. The system of claim 108, wherein said custom prosthetic liner is manufactured from a block copolymer material.
110. A system for producing a custom prosthetic liner that allows an amputee with a residual limb of changed shape and/or size to continue wearing an existing prosthetic socket, comprising:

a shape capture apparatus for capturing a 3-dimensional shape of said amputee's residual limb;

a shape capture apparatus for capturing a 3-dimensional shape of the interior of said existing prosthetic socket;

a processing device, said processing device running a computer program for generating a 3-dimensional electronic liner model by comparing the captured 3-dimensional shapes of said amputee's residual limb and said interior of said existing prosthetic socket, calculating a difference in size between the outer surface of said residual limb and the interior surface of said existing prosthetic socket, and automatically adjusting the thickness of said liner model as needed to make up for said difference in size;

an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired;

a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a manufacturing facility equipped to produce said custom prosthetic liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

111. The system of claim 110, wherein said shape capture apparatus for capturing the 3-dimensional shape of said residual limb is also used to capture the 3-dimensional shape of the interior of said existing prosthetic socket.

112. The system of claim 110, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

113. The system of claim 110, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is provided to said manufacturing facility via the Internet.

114. The system of claim 110, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

115. The system of claim 110, further comprising a storage means for temporarily storing data associated with the shape of said residual limb and said 3-dimensional electronic liner model.

116. The system of claim 115, wherein said storage means is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

117. The system of claim 110, further comprising a transmission device for remotely transmitting said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to said manufacturing facility.

118. The system of claim 117, wherein said transmission device is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth® card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

119. The system of claim 110, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

120. The system of claim 110, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

121. The system of claim 110, wherein said computer program also generates a viewable 3-dimensional electronic model of said existing prosthetic socket interior.

122. The system of claim 110, further comprising the ability to use said computer program to select liner materials and liner material properties.

123. The system of claim 110, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

124. The system of claim 123, wherein the number, location, and orientation of said accessories may also be specified.

125. The system of claim 123, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

126. The system of claim 125, wherein said additives include anti-microbial substances.

127. The system of claim 110, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

128. The system of claim 127, wherein said custom prosthetic liner is manufactured from a block copolymer material.

129. A system for producing a custom prosthetic liner that allows the residual limb of an amputee to be custom fit to a generic prosthetic socket, comprising:

- a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

- socket data representative of the 3-dimensional shape of an interior of said generic prosthetic socket;

- a processing device, said processing device running a computer program for generating a 3-dimensional electronic liner model by comparing the captured 3-dimensional shape of said amputee's residual limb and said interior of said generic prosthetic socket, calculating a difference in size between the outer surface of said residual limb and said interior surface of said generic prosthetic socket, and automatically adjusting the thickness of said liner model as needed to make up for said difference in size;

an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired;

a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a manufacturing facility equipped to produce said custom prosthetic liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

130. The system of claim 129, wherein said socket data is available as a result of the socket manufacturing process.

131. The system of claim 129, wherein said socket data is obtained by capturing the 3-dimensional shape of the interior of said generic prosthetic socket.

132. The system of claim 129, wherein said shape capture apparatus for capturing the 3-dimensional shape of said residual limb is also used to capture the 3-dimensional shape of the interior of said generic prosthetic socket.

133. The system of claim 129, wherein said generic socket is preselected from a group of generic prosthetic sockets, based on its size.

134. The system of claim 129, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen

computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

135. The system of claim 129, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is provided to said manufacturing facility via the Internet.

136. The system of claim 129, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

137. The system of claim 129, further comprising a storage means for temporarily storing data associated with the shape of said residual limb and said 3-dimensional electronic liner model.

138. The system of claim 129, wherein said storage means is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

139. The system of claim 129, further comprising a transmission device for remotely transmitting said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to said manufacturing facility.

140. The system of claim 129, wherein said transmission device is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a

WiFi card, a Bluetooth<sup>®</sup> card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

141. The system of claim 129, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

142. The system of claim 129, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

143. The system of claim 129, further comprising a separate system and computer program for facilitating the automatic configuration and purchasing of a medical device, said separate system and computer program accessible via said processing device.

144. The system of claim 143, wherein said generic socket may be selected from a database of said system and computer program for facilitating the automatic configuration and purchasing of a medical device.

145. The system of claim 129, wherein said computer program also generates a viewable 3-dimensional electronic model of said generic prosthetic socket interior.

146. The system of claim 129, further comprising the ability to use said computer program to select liner materials and liner material properties.

147. The system of claim 129, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

148. The system of claim 147, wherein the number, location, and orientation of said accessories may also be specified.



149. The system of claim 147, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

150. The system of claim 149, wherein said additives include anti-microbial substances.

151. The system of claim 129, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

152. The system of claim 151, wherein said custom prosthetic liner is manufactured from a block copolymer material.

153. A system for producing a custom prosthetic liner, comprising:

- a shape capture apparatus for capturing a 3-dimensional shape of an amputee's residual limb;

- a processing device running a computer program for generating a 3-dimensional electronic liner model from said 3-dimensional shape captured by said shape capture apparatus and liner parameters input by user of said system;

- an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model prior to generation of said 3-dimensional electronic liner model, data associated with said 3-dimensional residual limb model subsequently used in generating said 3-dimensional electronic liner model;

an interface for allowing a user of said system to operate said computer program to specify accessories to be included in/on said custom prosthetic liner;

optionally, an interface for allowing a user of said system to communicate with a separate system and computer program that facilitates the automatic configuration and purchasing of a medical device;

a means for temporarily storing data associated with a finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both;

a transmission device for allowing data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, to be remotely sent to a manufacturing facility equipped to produce said custom prosthetic liner;

a means at said manufacturing facility for receiving said data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, and for reading said data or converting said data into a readable form;

an apparatus for creating at least one custom mold component from said data;

a molding machine for forming said custom prosthetic liner from a mold incorporating said at least one custom mold component;

once said custom prosthetic liner is completed, a storage means for storing said data associated with said finalized version of said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, for future use; and

a storage system for storing said at least one custom mold component for future use, said storage system including a means for identifying a particular custom mold component with a particular amputee.

154. The system of claim 153, wherein said the number, location, and orientation of said accessories may also be specified.

155. The system of claim 153, wherein said accessories are selected from the group consisting of different types of suspension components, reinforcement, bladders (including inflatable bladders), additives, and, sensors.

156. The system of claim 155, wherein said additives include anti-microbial substances.

157. The system of claim 153, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

158. The system of claim 157, wherein said custom prosthetic liner is manufactured from a block copolymer material.

159. The system of claim 153, further comprising an interface for allowing a user of the system to select liner materials and liner material properties.

160. The system of claim 153, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen

computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

161. The system of claim 153, wherein said data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, is provided to said manufacturing facility via the Internet.

162. The system of claim 153, wherein said data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

163. A system for producing a custom prosthetic liner, comprising:

- shape data associated with an amputee's residual limb;

- a processing device in conjunction with a computer program for generating a 3-dimensional electronic liner model from said data and liner parameters input by a user of said system;

- optionally, an interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired, data associated with said 3-dimensional electronic residual limb model subsequently used in the generating said 3-dimensional electronic liner model;

- a means of providing data associated with said 3-dimensional electronic liner, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

164. The system of claim 163, wherein said shape data is in the form of a cast of said residual limb.

165. The system of claim 164, further comprising an electronic shape capture apparatus that is used to capture a 3-dimensional image of an interior of said cast.

166. The system of claim 163, wherein said shape data is in the form of measurements of said residual limb.

167. The system of claim 166, further comprising an interface for allowing a user of said system to input said measurements into said computer program.

168. The system of claim 163, wherein said processing device is selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

169. The system of claim 163, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

170. The system of claim 163, wherein electronic data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

171. The system of claim 163, wherein electronic data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

172. The system of claim 163, wherein said at least one custom mold component is produced by a computer-controlled machining device.

173. The system of claim 163, wherein said at least one custom mold component is created from a closed-cell foam material.

174. The system of claim 163, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

175. The system of claim 174, wherein said mold cavity is selected based only on its size.

176. The system of claim 163, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

177. The system of claim 163, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

178. The system of claim 177, wherein said custom prosthetic liner is manufactured from a block copolymer material.

179. The system of claim 163, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

180. The system of claim 163, further comprising the ability to select liner materials and liner material properties.

181. The system of claim 163, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

182. The system of claim 181, wherein the number, location, and orientation of said accessories may also be specified.

183. The system of claim 181, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

184. The system of claim 183, wherein said additives include anti-microbial substances.

185. The system of claim 163, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

186. A method of producing a custom prosthetic liner, comprising:

obtaining shape data associated with an amputee's residual limb;

providing a processing device in conjunction with a computer program for generating a 3-dimensional electronic liner model from said shape data and liner parameters input by a user of said system;

optionally, providing an interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired, data associated with said residual limb model subsequently used in generating said liner model;

providing data associated with said residual limb shape, said 3-dimensional electronic liner model, or both, to a manufacturing facility equipped to produce said custom liner;

creating at least one custom mold component from said data; and

using a molding machine to produce said custom prosthetic liner from a mold incorporating said at least one custom mold component.

187. The method of claim 186, wherein said shape data is obtained from an existing cast of said residual limb.

188. The method of claim 186, wherein said shape data is obtained by producing a cast of said residual limb.

189. The method of claim 188, further comprising electronically capturing a 3-dimensional image of an interior of said cast and providing electronic data associated therewith to said processing device.

190. The method of claim 189, wherein said image capturing is done at said manufacturing facility.

191. The method of claim 190, wherein said cast is sent to said manufacturing facility.

192. The method of claim 186, wherein said shape data is obtained by producing measurements of said residual limb.

193. The method of claim 192, further comprising entering said measurements into said system for use by said processing device.



194. The method of claim 186, wherein said processing device is selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

195. The method of claim 186, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

196. The method of claim 186, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

197. The method of claim 186, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

198. The method of claim 186, wherein said at least one custom mold component is produced from said data.

199. The method of claim 186, wherein said at least one custom mold component is created from a closed-cell foam material.

200. The method of claim 186, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

201. The method of claim 200, wherein said mold cavity is selected based on its size.

202. The method of claim 186, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

203. The method of claim 186, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

204. The method of claim 203, wherein said custom prosthetic liner is manufactured from a block copolymer material.

205. The method of claim 186, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

206. The method of claim 186, further comprising the ability to select liner materials and liner material properties.

207. The method of claim 186, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

208. The method of claim 207, wherein the number, location, and orientation of said accessories may also be specified.

209. The method of claim 207, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

210. The method of claim 209, wherein said additives include anti-microbial substances.

211. The method of claim 186, further comprising a means of communication with an automated system for configuring and purchasing a medical device.